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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/814,593

03/30/2004

Bernard Andreas

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

HOUSTON, ELIZABETH

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

02/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/814,593

Applicant(s)

ANDREAS ET AL.

Examiner

ELIZABETH HOUSTON

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 23-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 061906, 061907, 100104.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II (method) species b. (Figs. 7a-7e) in the reply filed on 08/24/07 is acknowledged.
2. Claims 2 and 23-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 08/24/07.
3. Regarding claim 2, it has been determined that the limitations in this claim are directed to a non-elected species of Fig. 6a-6h and therefore it has been withdrawn from further consideration.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the

Art Unit: 3731

requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/637,713, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. While the prior filed application provides support for a multiple stent delivery device, it does not provide support for a method that includes delivering a stent to a first branch and delivering a second stent to a second branch where the first and second meet at a bifurcation. Therefore the effective filing date for the purposes of applying prior art will be the filing date of the instant application, 03/30/2004.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3-13, 17-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Brucker et al. (US 2002/0193873).

7. Regarding claims 1, 3-11, Brucker discloses a method of treating one or more lesions including:

a. positioning a delivery catheter in the main branch and deploying a first stent (94 or 114) from the delivery catheter in the main branch (Para [0083]);

Art Unit: 3731

- b. positioning the delivery catheter in the side branch and deploying a second stent (74 or 116) from the delivery catheter in the side branch (Para [0084]);
- c. wherein the delivery catheter is not removed from the vessel between deploying the first and second stents (see Figs. 18-20).
- d. the delivery catheter is positioned through an opening (16) in a sidewall of the first stent to deploy the second stent (Fig. 20).
- e. the first and second stents each comprise a plurality of separable segments (where each strut is a segment and separable when the stent is expanded).
- f. the first stent has a different length than the second stent (Para [0080] where the second stent extends beyond the length of the first stent).
- g. the first stent is deployed before the second stent (Para [0083] and [0084]) and Figs. 18-20).
- h. the second stent is deployed before the first stent (For example see the stent configuration in Fig. 11 and 14).
- i. wherein the first stent and the second stent each have a portion in the main branch. (Fig. 14, 16, 17)
- j. further comprising adjusting the length of the first or the second stent before deploying the second stent while the delivery catheter remains in the vessel. (The length of the stent is chosen by the user before the stent is deployed

in the body. Deployment occurs while the delivery catheter remains in the vessel).

k. further comprising dilating at least one lesion in the vessel using an expandable member on the delivery catheter before deploying at least one of the first and second stents. (When the first stent is deployed it dilates at least one lesion before the second stent is deployed.)

8. Regarding claims 12, 13, 17-22, Brucker discloses a method including:

l. positioning a delivery catheter in the first branch and deploying a first stent from the delivery catheter in the first branch, (Fig. 18) a portion of the first stent being disposed across the bifurcation (Fig. 19);

m. positioning the delivery catheter in the second branch through an opening in a sidewall of the first stent and deploying a second stent from the delivery catheter, at least a portion of the second stent being disposed in the second branch; wherein the delivery catheter is not removed from the vessel between deploying the first and second stents (Fig. 20).

n. further comprising dilating the opening in the sidewall of the first stent by expanding an expandable member on the delivery catheter (34, Fig. 3, Para [0065]).

o. the first stent has a different geometry than the second stent (the first stent has a sidewall opening).

p. the first stent has a different length than the second stent (Para [0080] where the second stent extends beyond the length of the first stent).

Art Unit: 3731

- q. deploying the first stent comprises expanding an expandable member on the delivery catheter (where the expandable member is parts 116 and 118 combined).
- r. deploying the second stent comprises expanding the expandable member on the delivery catheter (where the expandable member is parts 116 and 118 combined).
- s. at least one of the first and second stents comprises a plurality of separable segments (where each strut is a segment and separable when the stent is expanded).
- t. further comprising dilating at least one lesion in the vessel using an expandable member on the delivery catheter before deploying at least one of the first and second stents. (When the first stent is deployed it dilates at least one lesion before the second stent is deployed.)

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brucker et al. (US 2002/0193873) in view of Loos et al (US 6,579,309).

Art Unit: 3731

11. Brucker discloses a method of treating a lesion in a bifurcation but does not disclose that the stent delivered to the main branch has an opening that is I-shaped or that the stent has first slots that are larger than second slots.

12. Loos discloses a stent that is intended to be delivered to a main branch of a bifurcation. The stent has side openings that are I-shaped (Fig. 3, for example where Arrows 19 and 20 are pointing). The stent has a plurality of first slots (I shaped openings) larger than a plurality of second slots (for example where 13 and 18) are pointing. The first slots are intended to be aligned with the bifurcation.

13. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the stent of Loos into the delivery device and method of Brucker. Brucker discloses the claimed method except for a stent with a flower shaped opening rather than an I-shaped opening. Loos shows that a stent with an I-shaped opening is an equivalent structure known in the art. Therefore, because the two stents were art recognized equivalents at the time of the invention was made, one of ordinary skill in the art would have found it obvious to substitute the I-shaped opening for the flower shaped opening, since substitution of one known element for another would have yielded predictable results.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

Art Unit: 3731

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731



Todd E. Manahan
SPC 3731